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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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09/030,571

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06/19/2006

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EXAMINER

FORMAN, BETTY J

ART UNIT

PAPER NUMBER

1634

DATE MAILED: 06/19/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

09/030,571

Applicant(s)

CANTOR ET AL

Examiner

BJ Forman

Art Unit

1634

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 07 April 2006.  
2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.  
3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 74-76,92-94,123,124 and 127-139 is/are pending in the application.  
4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.  
5) ☒ Claim(s) 74-76,92-94,123,124 and 136 is/are allowed.  
6) ☒ Claim(s) 127-135 and 137-139 is/are rejected.  
7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.  
8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.  
10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).  
11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All b) ☐ Some \* c) ☐ None of:  
1. ☐ Certified copies of the priority documents have been received.  
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).  
\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☐ Notice of References Cited (PTO-892)  
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)  
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_.  
4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_.  
5) ☐ Notice of Informal Patent Application (PTO-152)  
6) ☐ Other: \_\_\_\_\_.

## **DETAILED ACTION**

### ***Status of the Claims***

1. This action is in response to papers filed 7 April 2006 in which claim 127 was amended. The amendments have been thoroughly reviewed and entered. The previous rejection in the Office Action dated 16 February 2006 under 35 U.S.C. 112, first paragraph are withdrawn in view of the amendments. The previous rejections under 35 U.S.C. 102(b) are maintained. Applicant's arguments have been thoroughly reviewed and are discussed below.

Claims 74-76, 92-94, 123-124 and 136 are in condition for allowance.

Claims 127-135 and 137-139 are rejected.

### ***Claim Rejections - 35 USC § 112***

2. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

3. Claims 127-135 and 137-139 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 127-135 and 137-139 are indefinite in Claim 127 for the recitation "the four bases" because the recitation lacks proper antecedent basis in the claim.

### ***Claim Rejections - 35 USC § 102***

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

5. Claims 127-133, 135, 137-139 are rejected under 35 U.S.C. 102(b) as being anticipated by Holmes et al (WO 90/06045, published 14 June 1990).

Art Unit: 1634

Regarding Claim 127, Holmes et al discloses an array of probes wherein each probe comprises a single-stranded portion comprising a variable region (oligonucleotide to be sequenced) and a double-stranded portion (oligo-dT) wherein the probes are divided into four subsets wherein each subset a nucleic acid base occupies a defined number of positions (e.g. ddATP) and all other bases (T, C, G) occupy the remaining positions (page 14, lines 1-20; page 15, lines 15-35; and page 35, line 10—page 36, line 17).

Holmes describes a sequencing reaction using four mixtures wherein the primer and template are annealed to form a hybrid having a double stranded portion and a single strand portion. Upon extension of the primer using each ddNTP mix (e.g. "A mix"), the extended portion of the double strand comprises a defined number of the selected base (i.e. only one A is incorporated) and all the other positions of the extended portion are occupied by (T, C, G). Therefore, the extended hybrid of Holmes is encompassed by the claimed. The ddNTP of Holmes is a nucleotide base as claimed because the absence of the 3' hydroxyl does not alter the base. Hence, the ddNTP is a base as claimed.

Furthermore, prior to primer extension, the single stranded portion of the probes has the complement of the extension product described above. This complement comprises a region having a base at a defined number of positions (e.g. T position complementary to the incorporated A) and all other bases occupy the remaining positions.

Therefore, the hybrid, prior to extension comprises a single stranded region meeting the limitations of Claim 127 and the extended product comprises a double-stranded region having the limitations of Claim 127.

Regarding Claims 138 and 128, Holmes et al disclose the array wherein the probes are fixed to a solid support via a coupling agent e.g. biotin (page 8, lines 7- 11 and page 11, lines 23-26).

Regarding Claim 129, Holmes et al disclose the array wherein the probes are labeled (page 15, lines 15-35).

Art Unit: 1634

Regarding Claim 130, Holmes et al disclose the array wherein the label is a radioisotope or florescent molecule (page 13, line22-page 14, line 29).

Regarding Claim 131, Holmes et al disclose the array wherein the nucleic acids are DNA or RNA (page 2, lines 9-22).

Regarding Claim 132, Holmes et al disclose the array wherein the solids support is metal (page 4, lines 14-35).

Regarding Claim 133, Holmes et al disclose the array wherein the solid support is three-dimensional having multiple binding sites (page 5, line 19-page 7, line 9).

Regarding Claim 135, Holmes et al disclose the array wherein the probes comprise a base analog (i.e. biotintylated nucleotide at the end, page 8, lines 7- 11).

Regarding Claim 136, Holmes et al disclose the array wherein the double stranded portion includes a restriction site (page 18, lines 32-37).

Regarding Claims 137, Holmes et al disclose the array wherein the probes are fixed to a solid support via a coupling agent e.g. biotin (page 8, lines 7-11 and page 11, lines 23-26).

Regarding Claims 138, Holmes et al disclose the array wherein the probes are fixed to a solid support via a coupling agent e.g. biotin (page 8, lines 7- 11 and page 11, lines 23-26).

Regarding Claims 139, Holmes et al disclose the array wherein the probes are fixed to a solid support (page 8, lines 7- 11 and page 11, lines 23-26).

#### **Response to Argument**

6. Applicant states that the claims, as amended, define the incorporated base as one of four bases and asserts that one of skill in the art would recognize that the four bases include RNA nucleotides (A, U, C, G) or DNA nucleotides (A, T, C, G). Applicant's assertion is noted but is not found convincing. First, Applicant has not provided any evidence that one of skill in the art would recognize the asserted limitations. Therefore the assertion is deemed arguments of counsel.

The arguments of counsel cannot take the place of evidence in the record. In re Schulze, 346 F.2d 600, 602, 145 USPQ 716, 718 (CCPA 1965) (see, MPEP 716.01(c)).

Art Unit: 1634

Furthermore, it is noted that Applicant lists 5 nucleotide bases (A, U, T, C, G) that meet the limitations of the claims. Therefore, Applicant's arguments are not commensurate in scope with the claimed four bases.

Additionally, as stated above, the probes of Holmes, prior to ddNTP incorporation contain a single stranded portion having the complement to the subsequently extended portion. This complement does contains a selected base a defined number of positions (one) complementary to the incorporated ddNTP. Therefore, the hybrids of Holmes are encompassed by the claimed probes. It is noted that the claims do not define the selected nucleotide base as being part of the single stranded or double stranded portion. For this additional reason, the probes of Holmes are encompassed by the claimed probes.

7. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

#### **Conclusion**

8. Claims 74-76, 92-94, 123-124 and 135 are free of the prior art and may be placed in condition for allowance following resolution of the above rejections.

Art Unit: 1634

9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to BJ Forman whose telephone number is (571) 272-0741. The examiner can normally be reached on 6:00 TO 3:30.


If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ram Shukla can be reached on (571) 272-0735. The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547.

Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR) can now contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are available to answer your questions daily from 6 am to midnight (EST). The toll free number is (866) 217-9197. When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent Electronic Business Center will notify applicants of the resolution of the problem within 5-7 business days. Applicants can also check PAIR to confirm that the problem has been corrected. The USPTO's Patent Electronic Business Center is a complete service center supporting all patent business on the Internet. The USPTO's PAIR system provides Internet-based access to patent application status and history information. It also enables applicants to view the scanned images of their own application file folder(s) as well as general patent information available to the public.

For all other customer support, please call the USPTO Call Center (UCC) at 800-786-9199.

  
BJ Forman, Ph.D.  
Primary Examiner  
Art Unit: 1634  
June 15, 2006